IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

TROY ICKES,

5720 Highland Lane
Sunderland, MD 20689,

Plaintiff,

v.

DEPUY ORTHOPAEDICS, INC.,

700 Orthopaedic Drive
Warsaw, IN 46581,

DEPUY, INC.,

700 Orthopaedic Drive
Warsaw, IN 46581,

JOHNSON & JOHNSON,

One Johnson & Johnson Plaza
New Brunswick, NJ 08933,

JOHNSON & JOHNSON SERVICES, INC.,

One Johnson & Johnson Plaza
New Brunswick, NJ 08933,

and

JOHNSON & JOHNSON INTERNATIONAL,

One Johnson & Johnson Plaza
New Brunswick, NJ 08933,

Defendants.

CIVIL ACTION NO. _____

SUBJECT TO TRANSFER TO MDL 2244

COMPLAINT

COMES NOW, Plaintiff, Troy Ickes (the "Plaintiff"), by and through his undersigned attorneys and for his Complaint against Defendants DePuy Orthopaedics, Inc.; DePuy, Inc.; Johnson & Johnson; Johnson & Johnson Services, Inc.; and Johnson & Johnson International; (collectively, the "Defendants"), alleges as follows:

1. This lawsuit involves defective hip replacement components designed, manufactured, marketed, distributed, sold, and serviced by Defendants.

2. As a direct and proximate result of the installation of and expected, ordinary wear on the defective components in his right hip, Plaintiff has suffered and continues to suffer from numerous adverse health effects, including but not limited to the following:

a. Intractable pain in groin and lateral thigh;

b. Inability to walk without a cane;

c. Pseudotumors, one of them "massive," as described by his radiologist;

d. Extensive bone loss in his femur, acetabulum, and ischial tuberosity;

e. Parasthesia in his right leg;

f. Thyroid issues;

g. Dermatologic symptoms in the area of the defective components;

h. Metallosis;

i. Debris and fluid in the joint and surrounding tissues;

j. Marked distention of the right hip;

k. Revision surgery;

l. Copious brown fluids in his body secondary to metallosis;

m. Bell's palsy;

n. Vertigo;

o. Cobalt poisoning;

p. Chromium poisoning;

q. Failure of the revision surgery;

r. Second revision surgery;

s. Kidney cancer;

t. Necrotic tissue in his hip and leg; and

u. Permanent disability resulting from some or all the above.

3. The components at issue in this case were marketed by Defendants as the "DePuy Pinnacle" hip system (hereafter, "Pinnacle," the "Pinnacle System," or the "Pinnacle Device").

PARTIES

4. Troy Ickes (the "Plaintiff") is a citizen of the State of Maryland and resides in Sunderland, Maryland.

5. Defendant DePuy Orthopaedics, Inc. is an Indiana corporation with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Upon information and belief, Defendant DePuy Orthopaedics, Inc. is a wholly owned subsidiary of Defendant DePuy, Inc.

6. Defendant DePuy, Inc. is a Delaware corporation with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Upon information and belief, Defendant DePuy Inc. is a wholly owned subsidiary of Defendant Johnson & Johnson International.

7. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

8. Defendant Johnson & Johnson Services, Inc. is a New Jersey corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

9. Defendant Johnson & Johnson International is a New Jersey Corporation with its principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Upon information and belief, Defendant Johnson & Johnson International is a wholly owned subsidiary of Defendant Johnson & Johnson.

10. At all relevant times, each Defendant was the representative, agent, employee, or alter ego of the other Defendant, and in doing the things alleged herein was acting within the scope of its authority.

JURISDICTION AND VENUE

11. This Honorable Court has subject matter jurisdiction over the within action pursuant to 28 U.S.C. § 1332 because the Plaintiff and Defendants are citizens of different states and the amount in controversy exceeds the sum or value of $75,000.

12. This Honorable Court has personal jurisdiction over Defendants due to and based on Defendants' purposeful, continuous, and systematic contacts within the Commonwealth of Virginia, and because Plaintiff's claims arise out of events occurring in the Commonwealth of Virginia.

13. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events giving rise to Plaintiff's claims occurred in this judicial district.

BACKGROUND

14. The hip joint connects the thigh (femur) bone of a patient's leg to the patient's pelvis. The hip joint is often characterized as a ball and socket joint. The acetabulum is the cup

shaped socket portion of the hip and the femoral head (ball) at the top of the femur bone rotates within the curved surface of the acetabulum.

15. A total hip system replaces the body's natural joint with an artificial one, usually made from metal, plastic, or ceramic. A typical hip replacement system consists of four separate components: (1) a femoral stem, (2) a femoral head, (3) a liner (bearing surface), and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the metal femoral stem is implanted. The femoral head is usually a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joint that can rotate when it is placed inside a plastic, ceramic or metal liner that is attached to the interior portion of the metal acetabulum cup (socket) comprised of metal on its outer shell. When complete, the femoral stem anchors the metal femoral head that rotates within the liner sitting inside the acetabular cup.

16. Defendants developed, designed, tested, manufactured, distributed, and sold the Pinnacle Acetabular Cup System (the "Pinnacle Device") which is a hip bearing system to be used in a total hip replacement or revision surgery. The Pinnacle Device system includes two component parts: the liner and acetabular cup. Defendants developed, designed, tested, manufactured, and distributed at least four different metal acetabular cups and three different liners to be used as the Pinnacle Device. The acetabular cup is comprised of titanium metal on its outer shell and can be fixed to the bone with screws or without screws by growing into the bone with Defendants GriptonTM porous technology. The Pinnacle Device has three different liners to choose from, made of cobalt-chromium metal, polyethylene plastic or ceramic. One of the cobalt-chromium metal liners is the Ultamet® XL.

17. The Pinnacle Device is critically different than most hip replacement devices because a metal acetabular liner may be used instead of a polyethylene plastic acetabular liner. The Pinnacle Device with a metal liner, such as the Ultamet® XL, is a "metal-on-metal" device

since both articulating surfaces - the femoral head (ball) and acetabulum liner (socket) - are comprised of cobalt-chromium (CoCr) metal. Therefore, the metal-on-metal design forced metal to rub against metal with the full weight and pressure of the human body, creating metallic debris to be released into the Plaintiff's hip socket and blood stream. Because of Defendants' defective design for the Pinnacle Device, which caused the Pinnacle Device to contain unreasonably dangerous defects, hundreds of patients - including Plaintiff - have been forced to undergo surgeries to replace the failed hip implants.

18. The unreasonably dangerous defects existed when Defendants sold the Pinnacle Device.

19. Defendants' marketing material describe the Pinnacle Device as "the only product available that provides the option of choosing a polyethylene or metal insert for use with the same outer titanium cup that replaces the socket of the natural hip."

20. Defendants developed, designed, tested, manufactured, and distributed the metal and ceramic femoral heads that are used with the Pinnacle Device that directly contact the liner. The Articul/eze-M Spec Femoral Head and the aSphere M-Spec Femoral Head are metal femoral heads commonly used with the Pinnacle Device.

21. The Pinnacle Device is fully compatible with DePuy's complete line of advanced femoral stems that Defendants develop, design, test, manufacture, and distribute, such as the AML®, Prodigy®, SummitTM, Corail®, Tri-Lock®, and S-ROM femoral stems and sleeves.

22. The Pinnacle Device is a Class III medical device. Class III medical devices are devices that are implanted, that operate to sustain human life or are of substantial importance in preventing impairment of human health, or that pose potentially unreasonable risks to patients.

23. The Medical Device Amendments to the Food, Drug, and Cosmetics Act of 1938 ("MDA") require Class III medical devices, including the Pinnacle Device, to undergo premarket

approval by the FDA. Premarket approval is a process that obligates the manufacturer to design and implement a clinical investigation and submit the results of the investigations to the FDA.

24. Premarket approval is a rigorous process that requires a manufacturer to submit what is typically a multivolume application that includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties, and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of such device; samples or device components required by the FDA; and, a specimen of the proposed labeling.

25. The FDA may grant premarket approval only if it finds that there is reasonable assurance that the medical device is safe and effective and must weigh any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

26. A medical device on the market prior to the effective date of the MDA—a so-called "grandfathered" device—was not required to undergo premarket approval.

27. In addition, a medical device marketed after the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially equivalent" to a pre-MDA device (*i.e.*, a device approved prior to May 28, 1976). This exception to premarket approval is known as the "510(k)" process and simply requires the manufacturer to notify the FDA under section 510(k) of the MDA at least 90 days prior to the device's introduction on the market of the manufacturer's intent to market a device, and to explain the device's substantial equivalence to a pre-MDA predicate device. The FDA may then approve the new device for sale in the United States.

28. The MDA does not require an FDA determination that the device is in fact substantially equivalent to a grandfathered device.

29. Instead of assuring the safety of the Pinnacle Device through clinical trials, Defendants sought to market the Pinnacle Device without conducting any clinical trials by obtaining FDA approval under section 510(k). To that end, Defendants submitted a section 510(k) premarket notification of intent to market the Pinnacle Device.

30. By telling the FDA that the Pinnacle Device's design was "substantially equivalent" to other hip components and products on the market, Defendants were able to avoid the safety review required for premarket approval under FDA regulations, which includes clinical trials.

31. The FDA cleared the Pinnacle Device for sale by means of the abbreviated 510(k) process and consequently the FDA did not require the Pinnacle Device to undergo clinical trials.

32. The 510(k) notification for the Pinnacle Device includes Defendants' assertion that they believe the Pinnacle Device to be substantially equivalent to grandfathered devices - devices that were never required to be reviewed for safety and effectiveness.

33. Significantly, unlike the premarket approval process, the 510(k)-notification process does not call for scrutiny—or even clinical testing—of a device's safety and effectiveness.

34. A finding of substantial equivalence is not equivalent to a finding of a device's safety and effectiveness.

35. **THUS, THE FDA'S FINDING OF "SUBSTANTIAL EQUIVALENCE" HAD NOTHING TO DO WITH REVIEWING THE PINNACLE DEVICE'S SAFETY AND EFFECTIVENESS,** but rather was only a determination of equivalence to grandfathered devices that never underwent safety and effectiveness review.

36. Defendants sold approximately 150,000 Pinnacle Devices.

37. **DESPITE RECEIVING WELL OVER THIRTEEN HUNDRED REPORTED ADVERSE EVENTS, DEFENDANTS DID NOT RECALL OR NOTIFY THE PUBLIC OR HEALTH CARE INDUSTRY OF THE DEFECTIVE PROBLEMS; INSTEAD, DEFENDANTS CONTINUED TO MARKET THE PINNACLE DEVICE.**

38. Defendants have received well over 1,300 adverse event reports associated with the Pinnacle Device since 2002, and the number is growing. For example, from January 1, 2011 to March 31, 2011 alone, the FDA received over 250 self-reported adverse events regarding the Pinnacle Device (metal-on-metal). Reported symptoms range from pain, infection, inflammation, feeling as if hip is dislocating, heavy metal poisoning (metallosis) confirmed by blood tests resulting in eventual revision, ALVAL (Aseptic Lymphocytic Vasculitis Associated Lesion) fluid and necrotic tissue in and around the hip joint, catastrophic failure, premature wear, disarticulation, and disassembly.

39. In May 2002, shortly after Defendants began selling the Pinnacle Device, Defendants received two complaints. One reported that a patient had to undergo revision surgery to remove and replace the Pinnacle Device because the liner disassociated with the cup. The other reported revision surgery because the acetabular cup had loosened. DePuy closed their investigation of the filed complaints finding that "corrective action is not indicated."

40. Defendants have continued to receive hundreds of similar complaints since 2002 reporting that the Pinnacle Device had failed and forced patients to undergo painful and risky surgery to remove and replace the failed hip. By June 2006, Defendants had received 50 complaints related to the Pinnacle Device.

41. Consequently, Defendants were fully aware that the Pinnacle Device was defective and that dozens of patients already had been injured by the Pinnacle Device. Based on this information, Defendants should have recalled the Pinnacle Device as early as 2006. At a minimum,

Defendants should have stopped selling the defective implant when it became aware that it had catastrophically failed in patients. Over the next two years, patients continued to report failures of the Pinnacle Device. By the end of 2008, Defendants received more than 430 reports, and by the end of 2009, that number skyrocketed to almost 750.

42. Had Defendants conducted clinical trials of the Pinnacle Device before it was first released on the market in the early 2000's, they would have discovered at that time what they ultimately learned in and around 2007 - that the Pinnacle Device results in a high percentage of patients developing pain, metallosis, biologic toxicity, and an early and high failure rate due to the release and accumulation of metal particles in the patient's surrounding tissue when there is friction (wear or edge-loading) of the cobalt-chromium metal femoral head that rotates within the cobalt-chromium metal acetabular liner.

43. The metallic particulates released by friction of the metal-on-metal surfaces can become toxic, causing metallosis or cobaltism giving rise to pseudotumors or other conditions. The formation of metallosis, pseudotumors, and infection and inflammation causes severe pain and discomfort, death of surrounding tissue and bone loss, and a lack of mobility.

44. Despite the knowledge of the Pinnacle Device's defect and that it had failed hundreds of times, causing hundreds of patients to undergo the agony of another surgery, Defendants continued to market and sell the defective Pinnacle Device implant. In so doing, DePuy actively concealed the known defect from doctors and patients - including Plaintiff and his doctor - and misrepresented that the Pinnacle Device was a safe and effective medical device.

45. Despite this knowledge, Defendants failed to warn medical providers and/or their customers of the unreasonable dangers associated with the Pinnacle Device and allowed for the continued sale and implantation into patients' bodies.

46. To this day, Defendants continue to sell the defective Pinnacle Device to unsuspecting patients without any warning about the risks or the failures that have been reported over the years.

47. Defendants tout the metal-on-metal Pinnacle Device in brochures saying "the DePuy metal-on-metal (MoM) articulation system is leading the way in advanced technology. Through years of careful engineering, research and expertise, we've created a total hip replacement solution that offers low wear and high stability."

48. Defendants claimed that "DePuy Orthopaedics remains the leader in metal-on-metal technology, offering several advantages, including larger diameter bearings that can improve hip range of motion and stability. In fact, one study conducted since the device was approved in 2002 observed that an estimated 99.9 percent of Pinnacle Device components remain in use." One of the Pinnacle Device designers, William P. Barrett, MD, of Valley Orthopaedic Associates/Proliance Surgeons in Renton, WA, has been quoted in Defendants' marketing materials saying "the Pinnacle cup exhibited 99% survivorship at five years and, significantly, differences between patients, surgeons, femoral stems, head size, and articulation types did not affect survival."

49. Defendants advertised that "only Pinnacle Hip Solutions feature TrueGlideTM technology, allowing the body to create a thin film of lubrication between surfaces. The result is a smooth, more fluid range of natural motion." Defendants distributed a press release stating "the aSphere head, combined with DePuy's exclusive TrueGlide technology, facilitates a more fluid range of natural motion and up to 159 degrees range of motion."

50. Defendants advertised that "the PinnacleTM Acetabular Cup System is DePuy's premium product for acetabular indications and can address all existing pathologies."

51. Defendants advertised that "for the first time surgeons have the choice between high performance bearings which all work within the PinnacleTM Acetabular Cup System."

52. Other Pinnacle Device advertisements and brochures included pictures of a man on the beach in a wet suit carrying a surfboard and a man playing tennis (which specifically describes him as a bilateral replacement). There are pictures of women stretching outside before work or yoga, and a woman riding a stationary bike.

53. Defendants marketed the Pinnacle Device as high-performance hip replacements and as superior products that would allow patients to return to their more active lifestyles. Defendants also advertised the Pinnacle Device would last longer than other hip replacement products.

54. Several governmental regulatory agencies have recognized the problems that are caused by metal-on-metal implants such as the Pinnacle Device. For instance, The Medicines and Healthcare Products Regulatory Agency ("MHRA") in Britain investigated Defendants' metal-on-metal total hip replacement system after receiving widespread reports of soft tissue reactions and tumor growth in thousands of patients who had received these implants. MHRA has required physicians to establish a system to closely monitor patients known to have metal-on-metal hips by monitoring the cobalt and chromium ion levels in their blood and to evaluate them for related soft tissue reactions.

55. Similarly, the Alaska Department of Health recently issued a bulletin warning of the toxicity of Defendants' metal-on-metal total hip replacement systems. The State of Alaska, like the MHRA, identified the need for close medical monitoring, surveillance and treatment of all patients who had received these and similar metal-on-metal implants.

56. Defendants have known for years that implantation of their Pinnacle Device and other metal-on-metal total hip replacement systems results in metallosis, biologic toxicity, and an

early and high failure rate. Once the body is exposed to and absorbs the toxic metallic ions and particulate debris from the Pinnacle Device, inflammation occurs, causing severe pain, necrosis (death) of the surrounding tissue and bone loss. Pseudotumors also develop and grow as a direct and proximate result of the toxic metallic particles and ions released from the metal-on-metal hip components.

57. There is no non-surgical solution for elevated cobalt levels.

58. **THE DEFECTIVE PINNACLE DEVICE AND THE DEFENDANTS' CONDUCT CAUSED AND CONTINUES TO CAUSE INJURIES AND SUBSTANTIAL DAMAGES TO PLAINTIFF.**

59. In or around 2005, Plaintiff experienced severe and debilitating hip pain that caused him to be treated by C. Anderson Engh, M.D.

60. Dr. Engh determined Plaintiff needed a total hip replacement surgery.

61. On December 14, 2005, Dr. Engh performed a right total hip arthroplasty ("THA") with sciatic nerve neurolysis and subtrochanteric varus closing wedge derotational osteotomy at INOVA Mt. Vernon Hospital.

62. During hip replacement surgery, Dr. Engh implanted Plaintiff with several DePuy Pinnacle components in Plaintiff's right hip, including:

a. Acetabular Cup: DePuy PINNACLE ACETABULAR CUP, 56 mm;

b. Acetabular Liner: DePuy Pinnacle METAL INSERT, 36 mm x 56 mm;

c. Femoral Head: DePuy ARTICUL/EZE M METAL ON METAL FEMORAL HEAD, 36 mm.

63. After being implanted with the Pinnacle Systems, Plaintiff began to experience elevated levels of cobalt and chromium in his blood and fatigue around Plaintiff's THA, and in and around his right knee.

64. On December 19, 2019, due to ongoing problems with the THA, Plaintiff consulted with William Hamilton, M.D., who recommended additional surgery to Plaintiff's hip.

65. On June 25, 2020, Plaintiff underwent a painful, complex, and risky surgery (known as a "revision surgery") under the care of Dr. Hamilton at INOVA Mount Vernon Hospital in Alexandria, Virginia, to remove and replace the Pinnacle Device that had failed. Revision surgeries are generally more complex than the original hip replacement surgery, often because there is a reduced amount of bone in which to place the new hip implants. Revision surgeries also usually take longer than the original hip replacement surgery and the revision surgery has a higher rate of complications.

66. In the months that followed, Plaintiff experienced additional symptoms, leading him to seek additional testing and medical care. He also was diagnosed with kidney cancer.

67. The symptoms included discomfort and numbness in the right hip and leg due to pressure building from fluid accumulation in two pockets at the front and back of his right hip. This recurring issue necessitated six separate aspirations of the fluid between January 2021 and June 2021.

68. On April 8, 2021, Dr. Troy Sukhu performed a robot-assisted partial nephrectomy on Plaintiff's right kidney at Anne Arundel Medical Center in Annapolis, Maryland. Dr. Sukhu removed a Grade 2 clear cell renal cell carcinoma, 3.1 centimeters across, from Plaintiff's kidney. Upon information and belief, the tumor was caused by metallosis due to the initial implant of the metal-on-metal Pinnacle Device.

69. Plaintiff experienced and was diagnosed with hemarthrosis, or bleeding into the hip joint, which caused joint pain and swelling.

70. On April 23, 2021, during one of the six aspiration procedures, a physician's assistant removed multiple syringes of dark brown blood from the pockets of fluid. Analysis of the fluid revealed the presence of titanium, chromium, and cobalt.

71. In June 2021, at Potomac Urology in Falls Church, Virginia, Plaintiff underwent a pelvic angiogram to diagnose the cause of the hemarthrosis, which included draining more than half a liter of fluid from the pockets.

72. By June 2021, the pockets re-filled with fluid, causing additional pain to the Plaintiff. The hip was drained again in July 2021.

73. Plaintiff developed a football-sized pseudotumor and related necrosis, caused by metallosis due to the initial implant of the metal-on-metal Pinnacle Device, near one of the pockets of fluid, causing him enormous physical discomfort and emotional distress.

74. Plaintiff's physicians have determined that the pseudotumor and related necrosis will require a second revision surgery, scheduled for December 2021.

75. Had Plaintiff known that the Pinnacle Device would cause the symptoms he experienced and is experiencing, Plaintiff would have refused implantation of the Pinnacle Device.

76. As a direct and proximate result of the failure of his defective Pinnacle Device system due to its unreasonably dangerous defects, Plaintiff sustained and continues to suffer damages, including, but not limited to, past, present, and future pain and suffering, severe and possibly permanent injuries, emotional distress, disability, disfigurement, economic damages (including medical and hospital expenses) monitoring, rehabilitative and pharmaceutical costs, and lost wages and loss of future earnings capacity. As a result, Plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial.

77. As a direct and proximate result of the failure of his defective Pinnacle Device, Plaintiff has suffered, and will continue to suffer, symptoms, conditions, and procedures, including the following:

a. Intractable pain in groin and lateral thigh;

b. Inability to walk without a cane;

c. Pseudotumors, one of them "massive," as described by his radiologist;

d. Extensive bone loss in his femur, acetabulum, and ischial tuberosity;

e. Parasthesia in his right leg;

f. Thyroid issues;

g. Dermatologic symptoms in the area of the defective components;

h. Metallosis;

i. Debris and fluid in the joint and surrounding tissues;

j. Marked distention of the right hip;

k. Revision surgery;

l. Copious brown fluids in his body secondary to metallosis;

m. Bell's palsy;

n. Vertigo;

o. Cobalt poisoning;

p. Chromium poisoning;

q. Failure of the revision surgery;

r. Second revision surgery;

s. Kidney cancer;

t. Necrotic tissue in his hip and leg;

u. Permanent disability resulting from some or all of the above; and

v. Emotional distress due to pain, lack of confidence in his ability to walk comfortable and safely, and lack of confidence in his recovery from the revision surgery.

78. All the injuries and complications suffered by Plaintiff were caused by the defective design, warnings, construction, and unreasonably dangerous character of the Pinnacle Device that was implanted in him. Had Defendants not concealed the known defects, the early failure rate, the known complications, and the unreasonable risks associated with the use of the Pinnacle Device, Plaintiff's physician would not have used, and Plaintiff would not have consented to the use of, the Pinnacle Device in his total hip arthroplasty.

79. As a direct and proximate result of the failed DePuy Pinnacle System, Plaintiff was required to have a revision surgery on his right hip, suffered additional scar tissue, sustained elevated cobalt in his blood, and now has a right hip implant with decreased longevity.

80. Plaintiff has suffered personal injuries, including experiencing great pain and suffering, because of the defective DePuy Pinnacle System. Plaintiff continues to experience pain and suffering and will experience additional pain and suffering in the future.

COUNT I
NEGLIGENCE
(ALL DEFENDANTS)

81. Plaintiff repeats and incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

82. At all material times, Defendants had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control and/or distribution of the Pinnacle Device into the stream of commerce, including a duty to assure that the device would not cause those who had it surgically implanted to suffer adverse harmful effects from it.

83. Defendants failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control and/or distribution of the Pinnacle Device into interstate commerce, in that Defendants knew or should have known that this product created a high risk of unreasonable, dangerous side effects, thereby breaching their duty to consumers, including Plaintiff.

84. The negligence of Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a. Negligently designing the Pinnacle Device in a manner which was dangerous to those individuals who had the device surgically implanted;

b. Designing, manufacturing, producing, creating and/or promoting the Pinnacle Device without adequately, sufficiently, or thoroughly testing it;

c. Not conducting sufficient testing programs to determine whether or not the Pinnacle Device was safe for use;

d. Defendants herein knew or should have known that Pinnacle Device was unsafe and unfit for use by reason of the dangers to its users;

e. Selling the Pinnacle Device without making proper and sufficient tests to determine the danger to its users;

f. Negligently failing to adequately and correctly warn Plaintiff or his physicians, hospitals and/or healthcare providers of the dangers of the Pinnacle Device;

g. Negligently failing to recall their dangerous and defective Pinnacle Device at the earliest date that it became known that the device was, in fact, dangerous and defective;

h. Failing to provide adequate instructions regarding the safety precautions to be observed by surgeons who would reasonably and foreseeably come into contact with, and more particularly, implant the Pinnacle Device into their patients;

i. Negligently advertising and recommending the use of the Pinnacle Device despite the fact that Defendants knew or should have known of its dangerous propensities;

j. Negligently representing that the Pinnacle Device offered was safe for use for its intended purpose, when, in fact, it was unsafe;

k. Negligently manufacturing the Pinnacle Device in a manner which was dangerous to those individuals who had it implanted;

i. Negligently producing the Pinnacle Device in a manner which was dangerous to those individuals who had it implanted;

l. Negligently assembling the Pinnacle Device in a manner which was dangerous to those who had it implanted; and

m. Defendants under-reported, underestimated and downplayed the serious danger of the Pinnacle Device.

85. Defendants were negligent in the designing, researching, supplying, manufacturing, promoting packaging, distributing, testing, advertising, warning, marketing and sale of the Pinnacle Device in that they:

a. Failed to use due care in designing and manufacturing the Pinnacle Device so as to avoid the aforementioned risks to individuals that had the devices surgically implanted;

b. Failed to accompany their product with proper warnings;

c. Failed to accompany their product with proper instructions for use;

d. Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of the Pinnacle Device; and

e. Were otherwise careless and/or negligent.

86. Upon information and belief, Defendants continued to market, manufacture distribute and/or sell the Pinnacle Device to consumers, including Plaintiff, even though Defendants knew or should have known that the Pinnacle Device caused unreasonable, dangerous side effects which many users would be unable to remedy by any means, when there were safer alternative methods of hip replacements.

87. Defendants knew or should have known that consumers such as Plaintiff would suffer foreseeable injuries because of Defendants' failure to exercise ordinary care as described above.

88. At all material times, Defendants knew of the defective nature of the Pinnacle Device as set forth herein, and continued to design, manufacture, market and sell the device so as

to maximize sales and profits at the expense of public health and safety, and as such, Defendants' conduct exhibited a wanton and reckless disregard for human life; and further, upon information and belief, Defendants exhibited such an entire want of care as to establish that their actions were a result of fraud, evil motive, actual malice and a conscious and deliberate disregard of foreseeable harm to Plaintiff herein.

89. Wherefore, the Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT II
NEGLIGENCE *PER SE*
(ALL DEFENDANTS)

90. Plaintiff repeats and incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

91. The Pinnacle Device supplied by Defendants is an adulterated and/or misbranded product as defined by the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§331(a) and 333(a)(2) ("FD&C Act").

92. Plaintiff is within the class of persons the FD&C Act and regulations promulgated pursuant to it by the FDA are designed to protect, and the Plaintiff's injuries are the type of harm these statutes and regulations are designed to prevent.

93. Defendants were negligent *per se* in supplying the Pinnacle Device to the Plaintiff because it is an adulterated and/or misbranded product. As a direct and proximate result of Defendants' negligence, Plaintiff has suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, damages and economic loss in the future.

94. Wherefore, the Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT III
NEGLIGENT MISREPRESENTATION
(ALL DEFENDANTS)

95. Plaintiff repeats and incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

96. At the time Defendants manufactured, designed, marketed, sold and distributed the Pinnacle Device for use by Plaintiff, Defendants knew or should have known of the use for which the Pinnacle Device was intended and the serious risks and dangers associated with such use of the Pinnacle Device.

97. Defendants owed a duty to treating physicians and to the ultimate end-users of the Pinnacle Device, including the Plaintiff, to represent the risks of the Pinnacle Device accurately and truthfully. Defendants breached that duty by misrepresenting and/or failing to adequately warn Plaintiff's physicians, the medical community, Plaintiff, and the public about the risks of the Pinnacle Device, which Defendants knew or in the exercise of diligence should have known.

98. As a direct result of Defendants' conduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries and Defendants are liable to Plaintiff in an amount to be determined at trial.

99. Wherefore, the Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT IV
FRAUDULENT CONCEALMENT
(ALL DEFENDANTS)

100. Plaintiff repeats and incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

101. Defendants fraudulently concealed information with respect to the Pinnacle Device in the following particulars:

102. Defendants represented through the labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Pinnacle Device was safe, and fraudulently withheld and concealed information about the substantial risks of using the Pinnacle Device; and,

103. Defendants represented that the Pinnacle Device was safer than other alternative medications and fraudulently concealed information which demonstrated that the Pinnacle Device was not safer than alternatives available on the market.

104. Defendants had sole access to material facts concerning the dangers and unreasonable risks of the Pinnacle Device.

105. The concealment of information by Defendants about the risks of the Pinnacle Device was intentional, and the representations made by Defendants were known by Defendants to be false.

106. The concealment of information and the misrepresentations about the Pinnacle Device were made by Defendants with the intent that doctors and patients, including Plaintiff, rely upon them.

107. Plaintiff and his physicians relied upon the representations and were unaware of the substantial risks of the Pinnacle Device that Defendants concealed from the public, including Plaintiff and his physicians.

108. Plaintiff was injured as a direct and proximate result of Defendants' actions, omissions, and misrepresentations. Plaintiff has incurred and will continue to incur expenses as a result of using the Pinnacle Device.

109. Wherefore, the Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT V
BREACH OF EXPRESS WARRANTY
(ALL DEFENDANTS)

110. Plaintiff repeats and incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth herein.

111. Defendants expressly warranted to Plaintiff by and through Defendants and/or their authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for physicians, patients, Plaintiff, and the public, that the Pinnacle Device was safe, effective, fit, and proper for its intended use.

112. The Pinnacle Device does not conform to those express representations because the Pinnacle Device is not safe and has serious, life-threatening side effects.

113. In allowing the implantation of the Pinnacle Device, Plaintiff and his physician relied on the skill, judgment, representations, and express warranties of Defendants. These warranties and representations were false in that the Pinnacle Device was not safe and was unfit for the uses for which it was intended.

114. Defendants breached their warranty of the mechanical soundness of the Pinnacle Device by continuing sales and marketing campaigns highlighting the safety and efficacy of their product, while they knew of the defects and risk of product failure and resulting patient injuries.

115. As a direct result of Defendants' misconduct, Plaintiff has suffered and continues to suffer serious and permanent non-economic and economic injuries, and Defendants are liable to Plaintiff in an amount to be determined at trial.

116. Wherefore, the Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT VI
BREACH OF IMPLIED WARRANTY
(ALL DEFENDANTS)

117. Plaintiff repeats and incorporates by reference all preceding paragraphs and allegations of this Complaint as though fully set forth therein.

118. Defendants impliedly warranted to prospective purchasers and users, including Plaintiff, that the Pinnacle Device was safe, merchantable, and fit for the ordinary purposes for which said product was to be used.

119. Plaintiff reasonably relied upon the skill and judgment of Defendants as to whether the Pinnacle Device was of merchantable quality and safe and fit for its intended use.

120. Upon information and belief, and contrary to such implied warranties, the Pinnacle Device was not of merchantable quality or safe and fit for its intended use, because the product was and is unreasonably dangerous and unfit for the ordinary purposes for which it was used, as described above.

121. As a direct and proximate result of the breach of implied warranties by Defendants, Plaintiff suffered and will continue to suffer harm and economic loss as described above.

122. Wherefore, the Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages and punitive damages

where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT VII
FRAUD
(ALL DEFENDANTS)

123. Plaintiff repeats and incorporates by references all preceding paragraphs and allegations of this Complaint as though fully set forth therein.

124. Defendants made representations to Plaintiff and his physicians that their Pinnacle Device is a high-quality, safe, and effective hip replacement system.

125. Prior to marketing the Pinnacle Device that was implanted in Plaintiff, Defendants knew or should have known of the unreasonable dangers and serious health risks that such a metal-on-metal total hip replacement system posed to patients like Plaintiff.

126. As specifically described in detail above, Defendants knew that the Pinnacle Device subjected patients to early failure, painful and harmful physical reactions to toxic metallic particles and ions, death of tissue, bone loss and the need for explants and revision surgery.

127. Defendants' representations to Plaintiff and his physicians that their Pinnacle Device is high-quality, safe, and effective were false.

128. Defendants concealed their knowledge of the unreasonable risks and dangers associated with the use of the Pinnacle Device to induce Plaintiff and many thousands of others to purchase the system for surgical implantation in their bodies.

129. Neither Plaintiff nor his physicians knew of the falsity of Defendants' statements regarding the Pinnacle Device.

130. Plaintiff and his physicians reasonably relied upon and accepted as truthful Defendants' representations regarding the Pinnacle Device.

131. Plaintiff and his physicians had a right to rely on Defendants' representations and in fact did rely upon such representations. Had Plaintiff known of the high risks associated with the Pinnacle Device, he would not have purchased or allowed the Pinnacle Device to have been surgically implanted in him.

132. Any applicable statutes of limitation have been tolled by Defendants' knowing and active concealment and misrepresentations alleged here. Plaintiff and others were kept in ignorance of vital information, without any fault or lack of diligence on their part, had no knowledge of the above facts, and could not reasonably have discovered the fraudulent nature of Defendants' conduct.

133. Wherefore, the Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT VIII
CONSUMER FRAUD AND DECEPTIVE BUSINESS PRACTICES
(ALL DEFENDANTS)

134. Plaintiff repeats and incorporates by references all preceding paragraphs and allegations of this Complaint as though fully set forth therein.

135. Defendants are the researchers, developers, manufacturers, distributors, marketers, promoters, suppliers, and sellers of the Pinnacle Device, which they represented would be free from defects and fit for its intended purpose.

136. Defendants advertised, labeled, marketed, and promoted its product, the Pinnacle Device, representing the quality to health care professionals, the FDA, Plaintiff, Plaintiff's surgeon, and the public in such a way as to induce its purchase or use. More specifically,

Defendants represented that the Pinnacle Device was safe and effective for use by individuals such as Plaintiff or that it was safe and effective to treat Plaintiff's condition.

137. Defendants knew or should have known that the Pinnacle Device did not or would not conform to Defendants' representations and promises.

138. Defendants' concealed knowledge of the serious risks associated with the Pinnacle Device and concealed testing and research data, or selectively and misleadingly revealed or analyzed testing and research data.

139. Defendants' actions and conduct, as alleged in this Complaint, constitute unfair and/or deceptive acts or practices, in or affecting commerce, in violation of the provisions of Md. Code., Com. Law §§ 13-101 to 13-501.

140. As a direct and proximate result of Defendants' unfair and/or deceptive conduct, in or affecting commerce, Plaintiff is entitled to recover compensatory damages from Defendants and to recover their reasonably attorneys' fees, as provided for in Md. Code., Com. Law §§ 13-101 to 13-501.

141. Wherefore, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

COUNT IX
PUNITIVE DAMAGES
(ALL DEFENDANTS)

142. Plaintiff incorporates by references all preceding paragraphs and allegations of this Complaint as though fully set forth therein.

143. Plaintiff is entitled to punitive damages because Defendants' wrongful acts and/or omissions were willful and wanton conduct and in conscious and intentional disregard of and

indifference to the rights and safety of others. Defendants misled both the medical community and the public at large, including Plaintiff, by making false representations about the safety and efficacy of the Pinnacle Device and by failing to provide adequate instructions and training concerning its use.

144. Defendants downplayed, understated, and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of the Pinnacle Device, despite available information demonstrating that the Pinnacle Device could cause particles of cobalt and chromium to be deposited into Plaintiff's body and cause the device to loosen and become displaced or separate, causing serious harm to patients. Such risks and adverse effects could easily have been avoided had Defendants not concealed knowledge of the serious risks associated with the Pinnacle Device or provided proper training and instruction to physicians regarding use of the Pinnacle Device.

145. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety of the Pinnacle Device.

146. Defendants were or should have been in possession of evidence demonstrating that the Pinnacle Device caused serious side effects. Nevertheless, Defendants continued to market the Pinnacle Device by providing false and misleading information regarding its safety and efficacy.

147. Defendants failed to provide warnings that would have dissuaded health care professionals from using the Pinnacle Device, thus preventing health care professionals, including Plaintiff's surgeon, and consumers, including Plaintiff, from weighing the true risks against any benefits of using the Pinnacle Device.

148. Defendants failed to provide adequate training and instructions to surgeons, including Plaintiff's surgeon, who could have prevented failure of the Pinnacle Device causing serious harm and suffering to patients, including Plaintiff.

149. As a result of Defendants' conduct, Defendants are liable to Plaintiff in an amount to be determined at trial.

150. Wherefore, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, and severally, and requests compensatory damages and punitive damages where applicable, together with costs and interest, and any further relief as the court deems proper, as well as a trial by jury of all issues to be tried.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Troy Ickes, respectfully requests judgment in his favor and against Defendants, jointly and severally, as follows:

1. Judgment in favor of Plaintiff and against all Defendants, jointly and severally, for damages in excess of $10,000,000.00;

2. Compensation for both economic and non-economic losses, including but not limited to medical expenses, loss of earnings, pain and suffering, mental anguish, and emotional distress, in excess of $10,000,000.00;

3. Punitive and/or exemplary damages in such amounts as may be proven at trial;

4. Attorneys' fees, expenses and costs of this action;

5. Pre-and post-judgment interest as provided by law; and,

6. Any and all further relief, both legal and equitable, that the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial of his claims by jury to the extent authorized by law.

Dated: November 30, 2021

Respectfully submitted,

OSTER McBRIDE PLLC

/s/_____

Cameron McBride (Virginia Bar #35831)
Steven Oster (PHV Admission forthcoming)
2000 Duke Street, Suite 300
Alexandria, VA 22314
Telephone (912) 655-1736
Facsimile (703) 747-5862
cmcbride@ostermcbride.com
soster@ostermcbride.com

Counsel to Plaintiff